I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Famy Care Ltd submitted in 2012 an application for Zinnia P* (RH035) to be assessed with the aim of including Zinnia P in the list of prequalified medicinal products for contraception for women.

Zinnia P was assessed according to the 'Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process. The countries of origin of the assessors involved with Zinnia P were China, Ghana, Germany, Netherlands, South Africa, Switzerland, Tanzania and Zimbabwe.

Licensing status:

Zinnia P has been licensed / registered in the following countries:

Country	Marketing Authorization Number
Sweden	43219

2. Steps taken in the evaluation of the product

Sept 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2013 Feb 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 2013	The company's response letter was received.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2013	The company's response letter was received.
July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2013	The company's response letter was received.
Aug 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2013	Product dossier accepted (quality assurance)
21 Oct 2013	Zinnia P was included in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Famy Care Ltd. Unit II
1608/1609
G.I.D.C, Sarigam
396155 Valsad
Gujarat, India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

API manufacturers not inspected for GMP, as these are innovator sites located within a Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) country.

The FPP sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GLP /GCP. Previous site inspections by WHO showed acceptable outcome.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

http://www.who.int/prequal